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First Named Inventor:	PEDERSON, CHERYL A.		
Application No.:	09/729034	Confirmation No.:	4710
Filed:	December 4, 2000	Group Art Unit	3626
Title:	METHODS FOR MANAGING INFECTION RISK INCIDENT TO SURGICAL PROCEDURES IN HEALTH CARE PROVIDER ENVIRONMENTS		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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November 5, 2008 /Chris Johnson/

Date Signed by: Chris Johnson

Sir:

Applicant respectfully requests a Pre-Appeal Brief review of the rejection of claims 12-37 under 35 U.S.C. § 103 as being obvious over Mangram, Ormond-Walshe, Blume, Mushabac, Sullivan and Afsah, as set forth in the Final Office Action mailed August 5, 2008. Applicant maintains that the current rejections are improper for numerous reasons, many of which are outlined in previous Responses. However, for purposes of this Pre-Appeal Brief Review Request, Applicant has only focused on several significant errors in the Final Office Action. Applicant reserves the right to present other arguments in the Appeal Brief.

Applicant's independent claims recite methods, systems and computer-readable media that manage the risk or occurrence of surgical site infection incident to a surgical procedure. As one example, system claim 13 recites a system for managing such risk. The system of claim 13 comprises a perioperative process map of practices for the delivery of the surgical procedure. The map comprises a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices, wherein the health care delivery practices associated with the surgical procedure that pose a

source of measurable risk of surgical site infection are selectable for a given health care facility. At least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care practices. The system of claim 13 further comprises means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure, wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.

All pending claims (including claim 13) stand rejected as being obvious in view of a strained six-way combination of references. In particular, claim 13 stands rejected as being obvious over Mangram, Ormond-Walshe, Blume, Mushabac, Sullivan and Afsah. In the final Office Action, the Examiner recognized that a combination of Mangram, Ormond-Walshe, Blume and Mushabac fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claim 13 and other claims. For this feature, the Examiner cited Sullivan (specifically section **[0055]**) and argued that it would have been obvious to further modify the combination of Mangram, Ormond-Walshe, Blume and Mushabac in view of this passage of Sullivan.

Applicant traverses this argument for two reasons. First, the cited passage of Sullivan does not qualify as prior art to Applicant's claims. Second, the cited passage of Sullivan appears to be wholly irrelevant to the feature "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility."

Section **[0055]** of Sullivan is reproduced below:

> **[0055]** **FIG. 23** is another illustration of a screen display of a prescription medicine template.

The Examiner's assertion of Sullivan is inappropriate. This cited section of Sullivan in no way suggests any feature even remotely akin to "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claim 13 and other claims. On the contrary, FIG. 23 of Sullivan shows nothing more than a screen shot of a prescription medicine

template that has no relevance to a surgical procedure. Moreover, nothing in FIG. 23 appears to be selectable for a given health care facility, in any way.

In addition, section **[0055]** of Sullivan is not even prior art to Applicant's claims. The application for the Sullivan patent was filed on November 2, 2001, which is after Applicant's filing date of December 4, 2000. While Sullivan claims priority to a provisional application filed on November 2, 2000 ("the Sullivan Provisional"), the Sullivan Provisional only includes sixteen figures. Section **[0055]** of Sullivan and FIG. 23 are not included in the Sullivan Provisional. Accordingly, the cited passage of Sullivan is not entitled to the December 4, 2000 priority date.

In the Final Office Action, the Examiner stated that section **[0055]** and FIG. 23 are supported on page 19, lines 13-20, of the Sullivan Provisional. This section of Sullivan is reproduced below:

> The health care professional has access to a medical risk database 14 maintained on a data storage medium. The database 14 associates certain medical data in the patient data record 22 with additional medical care. The health care professional uses a data processor 16 to compare the medical data presented by the patient data record 22 with the medical data in the medical risk database 14 to identify whether medical data presented by the patient is associated with a risk of missed medical care opportunity. If so, information about additional medical care that would reduce the risk of a missed medical care opportunity is presented to the attending medical health care professional.

Clearly, this cited material from the Sullivan Provisional is not the same as the material of Sullivan relied upon by the Examiner. Nothing in this section includes any discussion of FIG. 23 of Sullivan. Moreover, like FIG. 23 of Sullivan, this material from the Sullivan Provisional fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claim 13 and other claims. On the contrary, the passage above describes a medical risk database that stores medical risks associated with a patient, but fails to suggest anything related to surgical procedures. In addition, the passage above fails to describe anything that is selectable for a given health care facility, in any way. The rejection of claim 13 and other claims is clearly erroneous, and should be overturned.

In the Final Office Action, the Examiner also recognized that the combination of Mangram, Ormond-Walshe, Blume, Mushabac and Sullivan fails to suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." For this feature, the Examiner cited column 6, lines 9-20, of Afsah. However, Afsah was filed after Applicant's current case, and this relied upon passage of Afsah is not supported by the Afsah Provisional date.

In the Office Action, the Examiner indicated that FIG. 16 of the Afsah Provisional supports the column 6, lines 9-20, of Afsah. However FIG. 16 of the Afsah Provisional is merely a graph that isn't even described in the Afsah Provisional. Accordingly, the relied upon passage at column 6, lines 9-20, of Afsah is not entitled to the Afsah Provisional date, and the cited passage of Afsah at column 6, lines 9-20 is not prior art to Applicant's claims.

Furthermore, regardless of whether Afsah is entitled to the priority date of the Afsah Provisional, Applicant also notes that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The passage of Afsah at column 6, lines 9-20, is reproduced below:

> Although the above method for determining the benchmark value of a particular indicator is preferred, there are other ways of identifying a benchmark value. For example, either the limit value of an indicator mandated by compliance regulations, or an historical baseline value can be used as the benchmark value for an indicator. Also the quartile approach can he used where the data group of indicator values is divided into quartiles and the worst value from the best quartile is selected as the benchmark value. Similarly, the best 10% approach can be used where the best 10% of the indicator value data group is selected and the worst value of the best 10% is designated as the benchmark value.

In this case, the so-called "benchmark value" is a benchmark for air admissions, used to help measure environmental performance. Indeed, Afsah is not even relevant to health care, much less the features of Applicant's claims. The passage above does not suggest any compliance indicator that indicates compliance with the one or more health care practices, as required by Applicant's claims, much less a compliance indicator that quantifies a measure of quality associated with delivery of corresponding health care delivery practices.

In addition to these clear errors, Applicant also notes that dependent claims 34-36 have not yet been addressed in any Office Action. In the Final Office Action and the previous Office Action, the Examiner failed to address claims 34-36, but merely stated that "as per claims 26-37[1], these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect. Claims 34-36 present features that the Examiner has not considered or addressed in any Office Action. Claims 34-36 read as follows:

> Claim 34: The method of claim 22, further wherein the compliance indicator defines a value within a pre-established quality scale.
>
> Claim 35: The method of claim 34, wherein the quality scale ranges from 1 to 10.
>
> Claim 36: The method of claim 22, further comprising generating a report that represents a compilation of measurement data associated with the surgical procedure.

None of these features of claims 34-36 have even been addressed in any Office Action to date.

CONCLUSION

In view of the clear errors identified above, Applicant respectfully requests that the current rejections be overturned at this Pre-Appeal Brief stage of the Appeal Process. Applicant reserves the right to present many other arguments in an Appeal Brief, if needed.

Please charge any additional fees or credit any overpayment to deposit account number 133723.

Date:
November 4, 2008

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[1] In the Final Office Action, the Examiner changed this portion to state "as per claims 26-35 and 37 these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." The Examiner mentioned claim 36 with claim 22, but again failed to address any of the features of claim 36 in any substantive discussion.